DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 9, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-78

Michael Brendan Mahaffey, Owner
The Best Fish Company, LLC d.b.a. Crab Fresh
2130 Harbor Avenue SW
Seattle, Washington 98126-2033

WARNING LETTER

Dear Mr. Mahaffey:

We inspected your firm located at 2130 Harbor Avenue SW, Seattle, Washington on June 5, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to Katharine M. Cissna Mahaffey, Bookkeeper at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your cooked crab to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.8(a). Your firm did not verify the adequacy of the time and temperature critical limits for refrigerated, vacuum packed crab at the cooking critical control point to control pathogen survival.

2. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan does not list appropriate critical control points for controlling the food safety hazard of *Clostridium botulinum* growth and toxin production in the finished product.

   Refrigeration of finished product is only a partial control for this hazard. While refrigeration below 38°F is adequate to control the growth of *Clostridium botulinum* type A and proteolytic B and F, additional controls must be in place to control *Clostridium botulinum* type E, and nonproteolytic B and F. We suggest you refer to *Fish & Fisheries Products Hazards & Controls Guide: Second Edition*, Chapter 13, *Clostridium botulinum* Toxin Formation, for more information on this hazard.

3. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan lists a critical limit, "water temperature not to exceed 40°", at the cooling critical control point that is not adequate to control pathogen growth. A more appropriate critical limit would refer to product temperature at this step, and would include a critical limit for time.

4. You must have a HACCP plan that lists monitoring procedures for each critical control point, in order to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan lists a monitoring frequency, "every time", at the cooling critical control point that is not adequate to control pathogen growth. We suggest you refer to *Fish & Fisheries Products Hazards & Controls Guide: Second Edition, Chapter 12, Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse,* for more information on this hazard.

5. You must take an appropriate corrective action when a deviation from a critical limit occurs, in order to comply with 21 CFR 123.7(a). Your firm did not take an appropriate corrective action to control pathogen growth when your process deviated from your temperature critical limit at the cooling critical control point. Your Cooling Logs for February 11 indicate temperatures of 60°F, your critical limit is 40°, yet there is no record that corrective action was taken. Your HACCP plan indicates that product will be destroyed if this parameter is exceeded.

6. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). Your firm did not monitor exclusion of pests and protection from adulteration with sufficient frequency to ensure control. Specific observations that pertain to these two areas of sanitation include:

   a. The building contains many gaps leading directly to the outside.
   b. There are unshielded lights in the processing room.

Of particular concern to the Food and Drug Administration is the fact that the observations noted above were also noted during our previous inspection of October 12, 1999. The Food and Drug Administration sent you a letter dated March 13, 2000. You failed to respond to that letter and the conditions found during our October Inspection continued. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to

include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Mr. Williamson at 425-483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement